Patient Study Calendar

Where are we,   and
Where are we going next?

Project Participants

Northwestern
- Warren Kibbe
- Renee Webb
- Sean Whitaker
- Rhett Sutphin
- Dong Fu
- Moses Hohman
- Eric Odulio
- Julie Zhu
- Andrew Winter
- John Osborne

Akaza Research
- Cal Collins
- Jaron Sampson
- Yufang Wang
- Shai Sachs
- Jun Xu
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SemanticBits
- Ram Chilukuri
- Padmaja Vedula
- Edmond Mulaire
- Joshua Phillips
- Vinay Kumar

Architecture Mentor
John Osborne
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VCDE Mentor
Hemant Shah

Use Cases, Architecture, Requirements and Review

Sharon Elcombe	Amy Funkhauser	Paul Courtney
Mayo	ECOG	Dartmouth

Peter Covitz	Doug Fridsma
George Komatsoulis	Linda Schmandt
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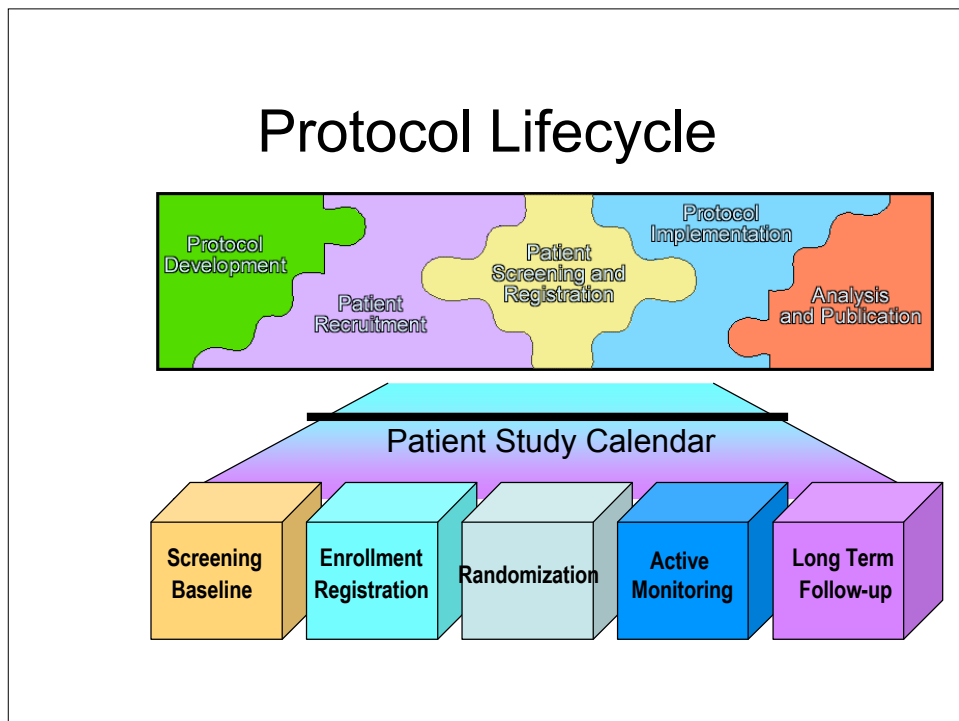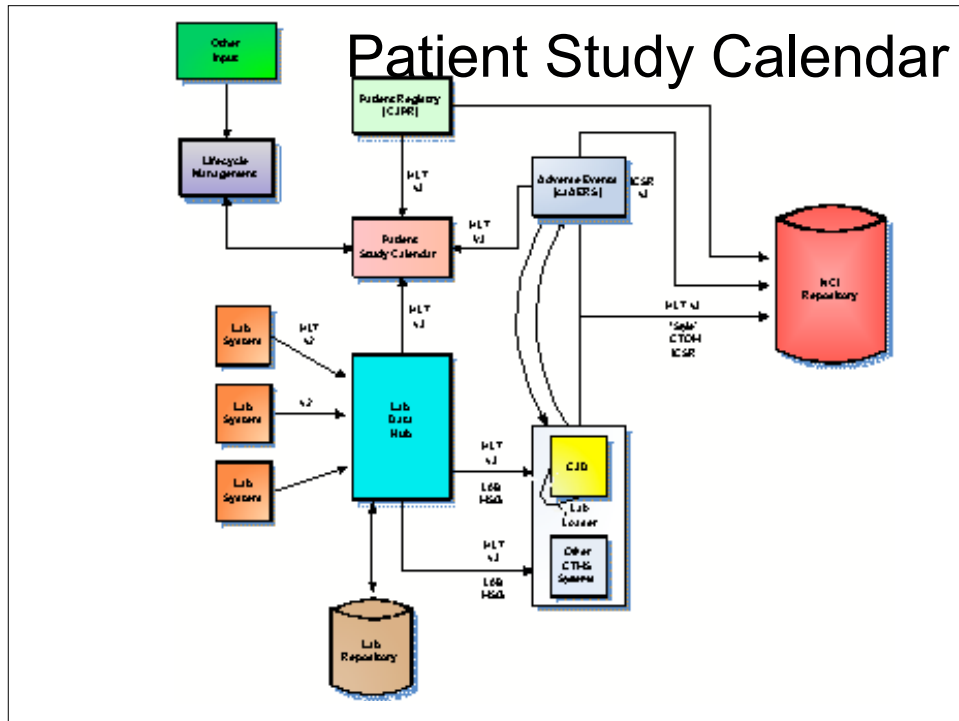| Mehul Shah	Karen Ryan	Susan Varghese
Julie Holtzople	Charlie Mead	Meg Gronvall

Requirements and Review Participants

- All Study Calendar SIG members!!

Patient Study Calendar

Protocol Lifecycle
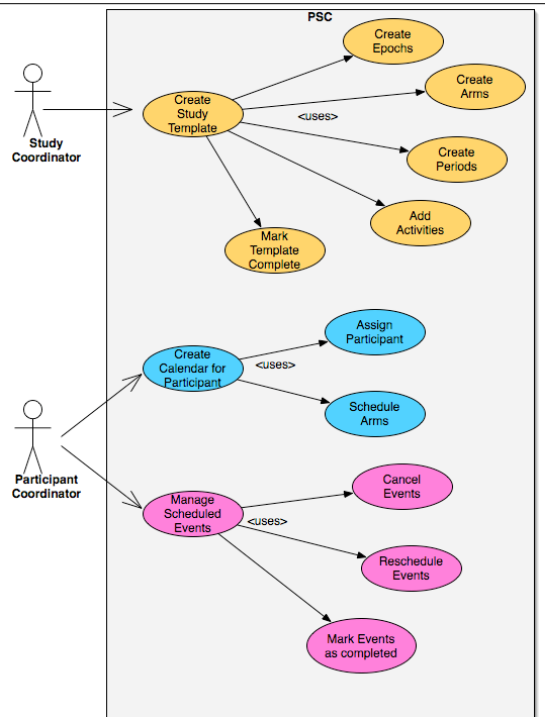
The Patient Study Calendar

Captures *activities* associated with a
  patient on a study

- Template for a Study
- Prospective
- Retrospective

Current Model

- BRIDG harmonized data definitions
- Used SDTM objects as appropriate
- BRIDG UML model (Enterprise Architect) at
  http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/studycalen
  dar/Final/PSC_BRIDG.EAP?cvsroot=studycalendar
- Implementation Model as an image
  http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/studycalen
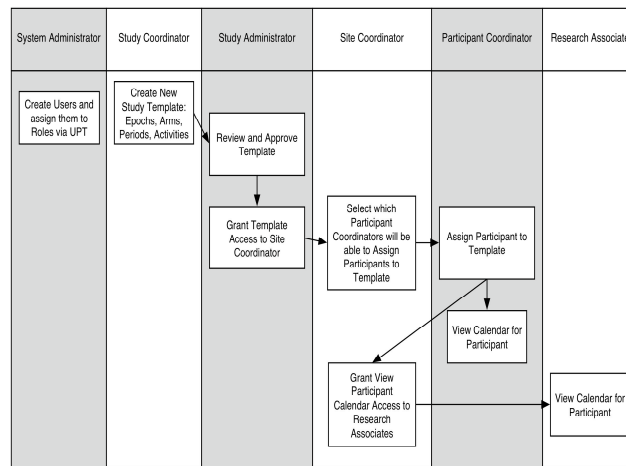 dar/Final/PSC_UML.bmp?cvsroot=studycalendar
- Main gForge site:
  https://gforge.nci.nih.gov/projects/studycalendar/

Specific Interactions Supported

Use Cases Addressed
(available at the PSC gForge site)

- Create new Study Template
- Create new period
- Create new activity
- Assign activities to periods
- View Study Template
- Mark Template as Complete
- Create Sites
- Assign Site Coordinators to Site
- Assign Sites to Template
- Assign Participant Coordinators to Site

- Assign Participant Coordinators to Template
- Assign Templates to Participant Coordinator
- Assign Participant to Study
- Create new Participant
- Create calendar for participant
- Manage Scheduled Events for a participant
- Create report of Scheduled Events

Actors and Interactions

System Administrator	Study Coordinator	Study Administrator	Site Coordinator	Participant Coordinator	Research Associate
Create Users and assign them to Roles via UPT	Create New Study Template: Epochs, Arms, Periods, Activities	Review and Approve Template			
		Grant Template Access to Site Coordinator	Select which Participant Coordinators will be able to Assign Participants to Template	Assign Participant to Template	
				View Calendar for Participant	
			Grant View Participant Calendar Access to Research Associates		View Calendar for Participant

Current Functionality

- Focused on standalone installation
- Uses the CSM for security
- Shell for creating participants and studies
- Ability to create a protocol template that includes Epochs, Arms, repeating elements of activities
- Ability to generate a calendar for a study or a participant on a study
- Ability to view planned events across a study or across a site [final release]

Where to get files

https://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/studycalendar/?cvsroot=studycalendar

- Wiki:

https://gforge.nci.nih.gov/plugins/wiki/index.php?id=31&type=g

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Known Use Cases
not yet addressed

- Interoperate with patient registries
- Interoperate with protocol registries
- Ability to export template as a file (ideally a serialized HL-7 v3, BRIDG-harmonized, message)
- Coupling with lab data/ caXchange

Obvious extensions

- Continued efficient data entry and review (batch rescheduling and periods of activities will be in the final release)
- Hub for exchange of study calendar templates (requires a way to generate and accepts a serialized representation of the template)

System Diagram